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Notice of Independent Review Decision

DATE OF REVIEW: July 13, 2011

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

LOS 2 days, lumbar laminectomy, discectomy, fusion w/instrumentation L4-S1. CPT Codes: 63030

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

AMERICAN BOARD OF ORTHOPAEDIC SURGEONS

REVIEW OUTCOME

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be:

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Medical records from the Carrier/URA include:

- Official Disability Guidelines, 2008
- L.L.C., 08/10/06
- Neurodiagnostic Associates, 01/10/07
- M.D., 04/11/07, 03/30/10, 06/24/10, 09/27/10, 12/14/10, 03/08/11, 06/14/11
- Imaging & Treatment Center, 04/11/07
- Diagnostic, 07/14/07
- M.D., 06/16/09, 06/17/09, 10/26/10, 12/14/10, 04/05/11, 05/24/11
- M.S., L.P.C., 07/17/09
- Pain Relief Clinic, 01/13/10
- Insurance Company, 06/07/11, 06/21/11

Medical records from the Provider include:

- M.D., 03/14/06
- Urgent Care Center, 03/15/06, 03/24/06
- L.L.C., 08/10/06
- M.D., 01/10/07
- M.D., 04/11/07, 08/29/07, 09/10/08, 12/08/08, 05/19/09, 03/30/10, 06/24/10, 09/27/10, 12/14/10, 03/08/11, 06/14/11
- Imaging & Treatment Center, 04/11/07
- Evaluation Center, 05/09/07
- M.D., 05/11/07, 08/17/07
- M.D., 05/21/07
- Diagnostic, 07/14/07
- D.C., 10/19/07
- M.D., 11/15/07
- M.D., 06/16/09, 06/17/09, 10/26/10, 04/05/11, 05/24/11
- M.S., L.P.C., 07/17/09
- Pain Relief Clinic, 01/13/10
- Insurance Company, 06/07/11
- Insurance Company, 06/21/11

PATIENT CLINICAL HISTORY:

The patient was employed as a xx who sustained an injury to his lower back on xx/xx/xx. It was initially described as a lumbar strain, although it escalated to where he was having subjective complaints of lumbar radiculopathy.

The patient had been seen by a number of physicians, including chiropractors, spine surgeons, and pain management physicians. The patient is presently proposed to have lumbar laminectomy, discectomy, fusion and instrumentation from L4 to S1. In addition to this, the patient will have a bone growth stimulator inserted.

I have reviewed the medical records provided to me and uphold the denial of the request for this surgery.

In reviewing his records, the patient has had several radiographic studies which do not demonstrate any significant pathology. The patient has multiple level bulging discs, but no frank disc herniation, thecal sac impingement or truly significant spinal stenosis. I base this on films that I have not seen, but this is the general drift of all the opinions.

In addition to this, the patient has had repeated EMG studies which are negative for significant radicular symptoms. Many of the physicians based their recommendations for surgery on a positive discogram, which was performed in 2007. The ODG Guidelines and current medical literature dictate that the discogram is not a valid diagnostic test. In this case, specifically, when the patient had his discogram at L3-4 and L4-5, the L5-S1 level could not be reached by whoever did it. It appears that the patient had a subligamentous injection in that there was little dye material in the nuclear area and most of the dye material was between the annulus and the posterior ligament. In this instance the dye was injected in between the posterior longitudinal ligament and the disc. This is obviously a quite painful ranking on a scale of 10-10. The resulting mass effect of the dye could create radicular symptoms similar to an epidural abscess. EMG studies were repeatedly negative, as were multiple MRI scans. The MRIs were actually alarmingly non-pathologic considering the radical surgical procedure proposed.

There was a rather passionate appeal by a chiropractor early on, which was intended to nullify the designated doctor examination by M.D., However, his points were not valid ,based solely on subjective analysis an could not really be taken seriously by a objective observer.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION.

Irrespective of this, this patient is an extremely poor surgical candidate. First of all, there is significant psychological overlay. The initial examinations noted on physical examination that the patient had evidence of symptom magnification. The patient had normal straight leg raisings when sitting, but exaggerated straight leg raisings when supine, as if he had been coached. In addition to this, the patient, from his psychological examination, has relatively unrealistic expectations of the surgery, which is flush with many problems. The patient continues to smoke. The patient is status post myocardial infarction, and is on Plavix. These, too, should be relative contraindications to this surgery. More importantly, the recent literature reveals that there has been significant manufacturer and pharmaceutical company influence on peer-review publications supporting lumbar spinal fusion/instrumentation. These recent revelations have only further brought into question the efficacy and appropriateness of lumbar fusion. This subject has been a vigorously debated "gray area", especially for treatment of back pain with no demonstratable objective evidence of instability. The latter is the case in this situation. Also, there appears to be an exponential growth in the number of patients receiving spinal instrumentation. This alarming trend is presently under investigation by the Department of Justice and the Office the Inspector General, because of the aforementioned financial incentivisation of implant industry. Again, in the past few years, there has been a 1500% increase in the percentage of cases having spinal instrumentation, when there has been concomitant overall decrease in the actual number of cases of spinal surgery per 10,000 in population. Coincidentally there is an 800-1000% increase in reimbursement in doing instrumentation versus a standard in situ decompressive laminectomy. This is unfortunately associated with a proportionate increase in morbidity and mortality. This is recently detailed in the New York Times on June 8, 2011, with specific references to Spine" and the Journal of the North American Spinal Association newsletter.

In addition, this peer review letter has shown that there has been very little evidence that spinal instrumentation improved clinical outcomes, but associated with significant increasing medical morbidity and mortality. In the workmen's compensation age group an article in Spine, April of 2009 or 2010, denoted that the leading cause of death in the workmen's compensation age group is opiate overdose. With an overall mortality rate within this group that accounts for 22% of all surgical deaths and an overall 1% mortality rate within the group.

Again, given this patient's evidence of unreal expectations, his cardiac history, his anticoagulate status, his inactivity, and that he has continued to smoke, in my opinion, this makes him not a candidate for surgery. This has even brought further into view by the fact that his physical examination and his radiologic studies do not demonstrate a surgical lesion. The patient's primary complaint is back pain with radiculopathy. Time and medical experience has demonstrated repeatedly that back surgery, especially fusion, is not indicated for a patient that has primarily back pain only. Fusions should be reserved for tumors, fractures, or patients that reveal gross instability. Intradiscal instability does not qualify as gross instability and usually is a surgeon's excuse to perform unnecessary surgery.

In summary, this patient is at extremely poor surgical candidate because of psychological and medical factors. The patient has no objective findings demonstrating he has a lesion that would be amenable to surgical intervention. The patient should NOT have the surgery. The patient may

require psychological counseling, to allow him to learn to live with his condition; pain management, using non-narcotic medications; use of an orthotic, such as a back brace or flexion bucket; and vocational re-education.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE
- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN
- INTERQUAL CRITERIA
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS, DISCUSSION WITH ORTOPAEDIC AND NEUROSURGICAL PEERS
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES
- MILLIMAN CARE GUIDELINES
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS
- TEXAS TACADA GUIDELINES
- TMF SCREENING CRITERIA MANUAL

- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE ("THE SPINE' CHALLENGE TO INTERGRITY IN SPINE PUBLICATION:A WHITEPAPER ARTICLE, JULY 2011, U.S SENATES REQUEST OF OFFICE OF INSPECTOR GENERAL DEPARTMENT H AND HS 2011 WALL STREET JOURNAL JUNE 2011, THE SPINE 'MORTALITY AFTER LUMBAR FUSION' APRIL 2009, JOURNAL OF AMERICAN MEDICAL ASSOCIATION RE: EFFICACY OF SPINAL FUSIONS>>)

- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (CURRENT CENTER FOR MEDICAR STUDIES: STUDY EFFICACY OF SPINAL INSTRUMENTATION IN MEDICARE AGE PATIENTS)